

February 26, 2013

RECALL NOTIFICATION

TO: Milex™ Diaphragm Customer

RE: **CooperSurgical Milex Wide-Seal Silicone Diaphragm Kit Lot Number 113367**

Dear Valued Milex Diaphragm Customer:

CooperSurgical manufactures the Milex Wide-Seal Silicone Diaphragm Kits. Recently, our ongoing quality surveillance discovered a packaging error in a single lot number of the Milex Diaphragm product line. The labels applied to this lot of packaging may not accurately reflect the size of the product contained in the package. Our records show that the label may indicate a 5mm larger size than the actual size of the product. The correct sizing of the diaphragm is molded into the device. The cause of this label issue has been investigated and the correction has been identified.

Accurate fit of the Milex Diaphragm is necessary for optimal effectiveness of the product. Note: There is no risk of illness or injury to the patient. A potential exists for a decrease in contraceptive efficacy if the diaphragm fit is not ideal. Use of spermicidal gel as indicated also contributes to the contraceptive efficacy of a diaphragm.

CooperSurgical records indicate you have been shipped some of the following specific lot number that is being recalled.

Recalled Lot Number:

Description	Part Number	Lot #	Manufactured Date
Diaphragm	MXWF65	113367	5/2/2012

If you have this affected lot number in your current inventory, please contact our Customer Service Department at 800-243-2974, or simply complete the attached form and fax to: 800-262-0105. Arrangements will be made to replace product in your possession at CooperSurgical's expense. Further instruction and disposition of product will be communicated to you at that time.

CooperSurgical deeply regrets the inconvenience that this problem has caused. Subsequent shipments of Milex Diaphragms have been thoroughly inspected, meet product release specification and will provide you with the product performance you have come to expect.

Sincerely,





**Request for Replacement of Recalled Product:
Milex™ Wide-Seal Silicone Diaphragm Kit**

Facility Name: _____ or Account #: _____

Billing Address: _____

City: _____ State: _____ Zip: _____

Contact Name: _____ Phone: _____

Fax Number: _____ *(Fax number is need so we can fax UPS return labels to you)*

Please supply the quantity of product you are returning for replacement.

Description	Part Number	Lot #	Manufactured Date	Quantity you are returning
Diaphragm	MXWF65	113367	5/2/2012	

Product may be picked up at CooperSurgical's expense at:

Address: _____ City: _____ St: _____ Zip: _____

Please send Replacement Product to: (Same location as above.)

Address: _____ City: _____ St: _____ Zip: _____

Fax to CooperSurgical, Inc., Attention Customer Service at 1-800-262-0105.

A Customer Service representative will be in contact with you shortly to provide you with a Return Merchandise Authorization Number (RMA) and an expected shipment date of replacement product.

CooperSurgical, Inc. | 95 Corporate Drive Trumbull, Connecticut 06611 | 1-800-243-2974

February 26, 2013

RECALL NOTIFICATION

TO: Milex™ Diaphragm Distributor

RE: **CooperSurgical Milex Wide-Seal Silicone Diaphragm Kit Lot Number 113367**

Dear Milex Diaphragm Distributor:

Recently, our ongoing quality surveillance discovered a packaging error in a single lot number of the Milex Diaphragm product line. The labels applied to this lot of packaging may not accurately reflect the size of the product contained in the package. Our records show that the label may indicate a 5mm larger size than the actual size of the product. The correct sizing of the diaphragm is molded into the device. The cause of this label issue has been investigated and the correction has been identified.

Accurate fit of the Milex Diaphragm is necessary for optimal effectiveness of the product. Note: There is no risk of illness or injury to the patient. A potential exists for a decrease in contraception efficacy if the diaphragm fit is not ideal. Use of a spermicidal gel as indicated also contributes to the contraceptive efficacy of the diaphragm.

Recalled Lot Number:

Description	Part Number	Lot #	Manufactured Date
Diaphragm	MXWF65	113367	5/2/2012

CooperSurgical has thoroughly investigated this error and has implemented appropriate corrective actions.

Effective immediately, you will need to forward the Recall Notification letter attached to the Milex Diaphragm Customers who received the lot in question and track the delivery of this letter for proof of receipt. The Recall Notification letter should be sent no later than March 31, 2013. Please send a copy of proof of delivery to:

CooperSurgical Inc.
Business Assurance
Attn: Regulatory Affairs Department
95 Corporate Drive
Trumbull, CT 06611

We deeply regret the inconvenience that this problem has caused. Subsequent shipments of Milex Diaphragms have been thoroughly inspected, meet product release specifications and will provide your customers with the product performance they have come to expect.

Sincerely,



February 26, 2013

RECALL NOTIFICATION

TO: Milex™ Diaphragm Customers

RE: **CooperSurgical Milex Wide-Seal Silicone Diaphragm Kit Lot Number 113367**

Dear Valued Milex Diaphragm Customer:

CooperSurgical manufactures the Milex Wide-Seal Silicone Diaphragm Kits. Recently, our ongoing quality surveillance discovered a packaging error in a single lot number of the Milex Diaphragm product line. The labels applied to this lot of packaging may not accurately reflect the size of the product contained in the package. Our records show that the label may indicate a 5mm larger size than the actual size of the product. The correct size of the diaphragm is molded into the device. The cause of this label issue has been investigated and the correction has been identified.

Accurate fit of the Milex Diaphragm is necessary for optimal effectiveness of the product. Note: There is no risk of illness or injury to the patient. A potential exists for a decrease in contraception efficacy if the diaphragm fit is not ideal. Use of a spermicidal gel as indicated also contributes to contraceptive efficacy of the diaphragm.

If you have this affected lot number in your current inventory, please contact your local CooperSurgical Distributor for product replacement.

Recalled Lot Number:

Description	Part Number	Lot #	Manufactured Date
Diaphragm	MXWF65	113367	5/2/2012

CooperSurgical deeply regrets the inconvenience that this problem has caused. Subsequent shipments of Milex Diaphragms have been thoroughly inspected, meet product release specifications and will provide you with the product performance you have come to expect.

Sincerely,

